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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,901	04/19/2004	Hovanes John Ter-Zakarian	12,616	2222

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

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09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,901	TER-ZAKARIAN, HOVANES JOHN	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed June 12, 2008 presents remarks and arguments submitted to the office action mailed March 19, 2008 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1, and 3-7 over Frenkel et al. (Increased urinary leukotriene E4 during febrile attacks in the hyperimmuno-globulinaemia D and periodic fever syndrome) in view of Sawyer et al. (6,797,723), Sims et al. (US Pat Applic. 2001/0053764– previously presented) and PDR (53rd edition 1999– previously presented) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

For Applicants convenience the rejections are restated below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 3- 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frenkel et al. (Increased urinary leukotriene E4 during febrile attacks in the hyperimmuno-globulinaemia D and periodic fever syndrome – previously presented) in view of Sawyer et al. (6,797,723), Sims et al. (US Pat Applic. 2001/0053764– previously presented) and PDR (53rd edition 1999– previously presented).

Frenkel et al. teaches "leukotreine receptor antagonists might offer a new therapeutic approach for patients with the hyperimmunoglobulinaemia D and periodic fever syndrome (abstract –*conclusion*)."

Sims et al. teaches that periodic fever syndrome include familial Mediterranean fever (p. 8, paragraph [0054]).

The references do not specifically teach the leukotreine receptor antagonists in a dosage between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years, nor the leukotreine receptor antagonists consisting of Zafirlukast or Singulair.

Sawyer et al. teaches leukotriene B4 receptor (LTB4) antagonists, useful for treatment of inflammatory diseases (abstract). Such inflammatory diseases are inclusive of bronchial asthma and familial Mediterranean fever (col 3 lines 48 and col 4 line 4). These leukotriene B4 receptor (LTB4) antagonists are adminstered orally and in the form of a tablet (col 115 lines 32 and 47). The amount of the leukotriene B4 receptor (LTB4) antagonists in oral form is 1 to about 1000 milligrams per day.

The PDR (53rd edition 1999) teaches that singular tablets are orally active leukotriene receptor antagonist (p. 1886 Description) useful in treating inflammatory diseases such as asthma. The recommended dosage amount for adolescents and adults 15 years of age and older is 10 mg tablets daily and for pediatric patients 6 to 14 years of age in one 5 mg. Chewable tablet daily (p. 1889 Dosage and administration).

Additionally, the PDR (53rd edition 1999) teaches that Zafirlukast is a selective peptide leukotriene receptor antagonist (see p. 3402 Description) useful in treating

asthma. The recommended oral dosage of Zafirlukast is 20 mg twice daily in adult and children 12 years and older.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to employ a leukotriene receptor antagonist of in the dosage amount between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years, and the leukotreine receptor antagonists consisting of Zafirlukast or Singulair. Further, it would have been obvious to lower the dosage of Zafirlukast in children because it is known that recommended children's intake of drugs are at lower dosages than adults. This is further distinguished by PDR's teachings that singular, a leukotriene receptor antagonist, is given to adults and children at different concentrations. The motivation to use a leukotriene receptor antagonist of Frenkel et al. in the dosage amount between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years is because Sawyer et al. teaches leukotriene B4 receptor (LTB4) antagonists, useful for treatment of inflammatory diseases (abstract). Such inflammatory diseases are inclusive of bronchial asthma and familial Mediterranean fever (col 3 lines 48 and col 4 line 4). These leukotriene B4 receptor (LTB4) antagonists are administered orally and in the form of a tablet (col 115 lines 32 and 47). The amount of the leukotriene B4 receptor (LTB4) antagonists in oral form is 1 to about 1000 milligrams per day and the PDR teaches that the said leukotriene receptor antagonist are therapeutically effective in the dosage range claimed, administered orally, on a daily basis, and to patients in the claimed age range. Therefore, a skilled artisan would have reasonable expectation of successfully

producing a therapeutically effective oral pharmaceutical formulation in the dosage range claimed.

Response to Arguments

Applicant's arguments filed on June 12, 2008 have been fully considered.

Applicant argues the Sawyer reference fails to teach the dosage amounts of LTRA, of as long as the FMF symptoms continue, nor the specific LTRA.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is reasonable suggestion by the prior art references that a skilled artisan would have expected a leukotreine receptor antagonist would have been useful in treating patients with familial Mediterranean fever. Frenkel et al. teaches "leukotreine receptor antagonists might offer a new therapeutic approach for patients with the hyperimmunoglobulinaemia D and periodic fever syndrome (abstract –*conclusion*)." Additionally, Sawyer et al. teaches leukotriene B4 receptor (LTB4) antagonists, useful for treatment of inflammatory diseases (abstract). Such inflammatory diseases are inclusive of bronchial asthma and familial Mediterranean fever (col 3 lines 48 and col 4

line 4). These leukotriene B4 receptor (LTB4) antagonists are administered orally and in the form of a tablet (col 115 lines 32 and 47). The amount of the leukotriene B4 receptor (LTB4) antagonists in oral form is 1 to about 1000 milligrams per day.

Examiner respectfully reiterates, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to employ a leukotriene receptor antagonist in the dosage amount between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years, and the leukotreine receptor antagonists consisting of Zafirlukast or Singulair. Further, it would have been obvious to lower the dosage of Zafirlukast in children because it is known that recommended children's intake of drugs are at lower dosages than adults. This is further distinguished by PDR's teachings that singular, a leukotriene receptor antagonist, is given to adults and children at different concentrations.

Applicant's arguments are not persuasive.

. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617